



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Ashley J. Birkett ) PATENT  
Serial No.: 09/930,915 ) Attorney Docket  
Filed: August 15, 2001 ) ICC-102.2  
For: IMMUNOGENIC HBc CHIMER ) (4564/81175)  
PARTICLES HAVING ENHANCED )  
STABILITY ) Group Art No.  
Examiner: Michael McGaw ) 1648

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner For Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Dear Sir:

Additional art that may be material to the prosecution of this application has come to the attention of the applicants. Thus, pursuant to 37 C.F.R. §1.97, a list of documents that may be material to the examination of this application is provided on the attached Form PTO-1449. Listed Documents B1-B18 are U.S. patents, Documents B18-B30 are foreign patents or applications, and Documents B31-B85 are articles. Copies of Documents B1-B85 are bound in three volumes and are enclosed herewith.

Also separately enclosed, but not listed on Form PTO-1449, are copies of four Office Actions from co-pending application Serial No. 09/931,325 mailed February 10, 2003, October 20, 2003, January 28, 2004 and March 9, 2004, respectively. Those copies are marked as Exhibits A, B, C and D, respectively.

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No inferences should be drawn that the attached list represents a comprehensive investigation, or that any material disclosed is equivalent to the subject invention. In addition, none of the documents that have publication dates prior to the priority date of the above application anticipate the invention in this application.

The cited documents disclose numerous specific features. There has been no attempt to list each and every feature disclosed by each document. The Examiner is requested to review the documents and determine the extent of the materiality of the document disclosures with respect to the present invention.

The discussion of any art and the citation of any document herein is not to be construed as an admission that the art or document disclosure is necessarily within the invention field of endeavor, that the art or document disclosure is necessarily prior in time to a particular date which may be relevant to the instant patent application, and/or that the art or document disclosure is otherwise necessarily prior art as defined by the patent law with respect to the instant invention and application.

Also, there is reserved the right to later set forth how the instant invention is distinguished over the disclosure of any document or other art, including the disclosures of the art and documents recited herein, that may be cited by the Examiner in rejecting a claim in the instant patent application.

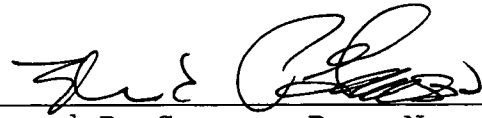
The recitation herein of the art and documents is not to be construed as an assertion that more pertinent art could not possibly be in existence.

The fee as set forth in 37 CFR § 1.17p is also enclosed. No further fee or petition is believed to be necessary. However, should any further fee be needed, please

charge our Deposit Account No. 23-0920, and deem this paper to be the required petition.

The Examiner is requested to phone the undersigned should any questions arise that can be dealt with over the phone to expedite this prosecution.

Respectfully submitted,

By   
Edward P. Gamson, Reg. No. 29,381

Enclosures

Form PTO-1449 and Bound Art, three volumes  
Exhibits A-D  
Fee  
Self-addressed Post Card

WELSH & KATZ, LTD.  
120 South Riverside Plaza, 22nd Floor  
Chicago, Illinois 60606  
Phone (312) 655-1500  
Fax No. (312) 655-1501

CERTIFICATE OF MAILING

I hereby certify that this Supplemental Information Disclosure, Form PTO-1449, Exhibits A-D and Bound Art are being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Mail Stop DD, Commissioner For Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on May 7, 2004.

  
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(Rev. 5/92) Comparable to Form PTO-1449 <b>MAY 10 2004</b> PATENT & TRADEMARK OFFICE		U.S. Department of Commerce Patent and Trademark Office		Atty. Docket No. ICC-102.2 (4564-81175)		Serial No. 09/930,915	
INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)				Applicants Ashley J. Birkett			
Filing Date August 15, 2001				Group 1648			
U.S. PATENT DOCUMENTS							
*Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate	
	B1	4,539,205	09/03/1985	Goodman, et al.	514	45	
	B2	4,643,992	02/17/1987	Goodman, et al.	514	45	
	B3	4,767,842	08/30/1988	Stevens	530	324	
	B4	4,987,237	01/22/1991	Myers, et al.	549	222	
	B5	5,011,828	04/30/1991	Goodman, et al.	514	45	
	B6	5,023,179	06/11/1991	Lam, et al.	435	172.3	
	B7	5,057,540	10/15/1991	Kensil, et al.	514	25	
	B8	5,093,318	03/03/1992	Goodman, et al.	514	45	
	B9	5,110,732	05/05/1992	Benfey et al.	435	172.3	
	B10	5,297,441	03/29/1994	Smith et al.	73	860	
	B11	5,387,744	02/07/1995	Curtiss, III et al.	424	235.1	
	B12	5,618,988	04/08/1997	Hauptmann, et al.	800	205	
	B13	5,656,472	08/12/1997	Ausich et al.	435	193	
	B14	5,679,880	10/21/1997	Curtiss, III et al.	800	205	
	B15	5,709,879	01/20/1998	Barchfeld, et al.	424	450	
	B16	5,888,799	03/30/1999	Curtiss, III	435	252.3	
	B17	6,024,961	02/15/2000	Curtiss, III et al.	424	200	
	B18	6,086,901	07/11/2000	O'Hagan, et al.	424	283.1	
FOREIGN PATENT DOCUMENTS							
	Document Number	Date	Country	Class	Subclass	Translation	
						Yes	No
	B19	GB 2,122,204 A	01/11/1984	GB			
	B20	WO 91/13922	09/19/1991	PCT			
	B21	EP 399 843 B1	11/28/1990	EP			
	B22	WO 95/17210	06/29/1995	PCT			
	B23	EP 421635 B1	04/10/1991	EP			
	B24	WO 96/02555	02/01/1996	PCT			
	B25	WO 96/33739	10/13/1996	PCT			
	B26	EP 671,948 B1	09/20/1995	EP			
	B27	EP 689,454 B1	01/03/1996	EP			
	B28	WO 99/07839	02/18/1999	PCT			
/Bo Peng/				Date Considered 07/02/2010			
*Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Indicate copy of this form with each communication to applicant.							

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FOREIGN PATENT DOCUMENTS							
B29	WO 99/52549	10/21/1999	PCT				
B30	WO 01/41759	06/14/2001	PCT				
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
B31	BENFEY et al., "Regulated Genes in Transgenic Plants", <i>Science</i> (April 1989) 244:174-181						
B32	BIRKETT et al., "A Modified Hepatitis B Virus Core Particle Containing Multiple Epitopes of the <i>Plasmodium falciparum</i> Circumsporozoite Protein Provides a Highly Immunogenic Malaria Vaccine in Preclinical Analyses in Rodent and Primate Hosts", <i>Infection and Immunity</i> (December 2002) 70(12):6860-6870						
B33	BLACK, et al., "Antibody Response to the M2 Protein of Influenza A Virus Expressed in Insect Cells", <i>J. of General Viro.</i> (1993) 74:143-146						
B34	COLUCCI et al., "Identification of a Major Hepatitis B Core Antigen (HBcAg) Determinant by Using Synthetic Peptides and Monoclonal Antibodies", <i>J. of Immunology</i> (December 1988) 141:4376-4380						
B35	CREGG et al., " <i>Pichia pastoris</i> as a Host System for Transformation", <i>Molecular and Cellular Biology</i> (December 1985) 5(12): 3376-3385						
B36	CREGG et al., "High-Level Expression and Efficient Assembly of Hepatitis B Surface Antigen in the BMethylotrophic Yeast, <i>Pichia Pastoris</i> ", <i>Bio/Technology</i> (May 1987) 5:479-485						
B37	DEIKMAN et al., "Interaction of a DNA Binding Factor with the 5'-Flanking Region of an Ethylene-Responsive Fruit Ripening Gene from Tomato", <i>EMBO J.</i> (1988) 7(11):3315-3320						
B38	DEIKMAN et al., "Organization of Ripening and Ethylene Regulatory Regions in a Fruit-Specific Promoter from Tomato", <i>Plant Physiol.</i> (1992) 100:2013-2017						
B39	DELPEYROUX et al., "A Poliovirus Neutralization Epitope Expressed on Hybrid Hepatitis B Surface Antigen Particles", <i>Science</i> (July 1986) 233:472-475						
B40	DIRITA et al., "Deletion Analysis of the Mannopine Synthase Gene Promoter in Sunflower Crown Gall Tumors and <i>Agrobacterium tumefaciens</i> ", <i>Mol. Gen. Genet.</i> (1987) 207:233-241						
B41	ENGELHARD et al., "The Insect Tracheal System: A Conduit for the Systemic Spread of <i>Autographa Californica</i> M Nuclear Polyhedrosis Virus", <i>Proc. Natl. Acad. Sci., USA</i> (April 1994) 91:3224-3227						
B42	GALIBERT et al., "Nucleotide sequence of the hepatitis B virus genome (subtype ayw) cloned in <i>E. coli</i> ", <i>Nature</i> (October 1979) 281:646-650						
B43	GALIBERT et al., "Nucleotide Sequence of a Cloned Woodchuck Hepatitis Virus Genome: Comparison with the Hepatitis B Virus Sequence", <i>J. Virol.</i> (January 1982) 41(1):51-65						
B44	GRAHAM et al., "A New Technique for the Assay of Infectivity of Human Adenovirus 5 DNA", <i>Virol.</i> (1973) 52:456-467						
B45	"IUPAC-IUB Commission on Biochemical Nomenclature A One-Letter Notation for Amino Acid Sequences <sup>1-3</sup> Tentative Rules", <i>J. Biol. Chem.</i> (July 1968) 243(13):3557-3559						
B46	JEGERLEHNER et al., "A Molecular assembly system that renders antigens of choice highly repetitive for induction B cell responses", <i>Vaccine</i> 20 (2002) 3104-3112						
B47	JEGERLEHNER et al., "Influenza A Vaccine based on the Extracellular Domain of M2: Weak Protection Mediated via Antibody - Dependent NK Cell Activity", <i>The Journal of Immunology</i> , 2004, 172: 5598-5605						
B48	KELLER et al., "Specific Expression of a Novel Cell Wall Hydroxyproline-Rich Glycoprotein Gene in Lateral root Initiation", <i>Genes &amp; Development</i> (1989) 3:1639-1646						
B49	LAMB et al., " <i>In Vitro</i> Influenza Virus-Specific Antibody Production in Man: Antigen-Specific and HLA-Restricted Induction of Helper Activity Mediated by Cloned Human T Lymphocytes", <i>J. of Immunology</i> (October 1982) 129(4):1465-1470						
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	B50	LAZDINA et al., "Priming of Cytotoxic T Cell Responses to Exogenous Hepatitis B Virus Core Antigen is B Cell Dependent", <i>J. of General Virol.</i> (2003) <b>84</b> :139-146					
	B51	LINDSTROM et al., "Expression of Soybean Lectin Gene Deletions in Tobacco", <i>Developmental Genetics</i> (1990) <b>11</b> :160-167					
	B52	LONDONO et al., "Immunisation of Mice Using <i>Salmonella typhimurium</i> Expressing Human Papillomavirus Type 16 E7 Epitopes Inserted into Hepatitis B Virus Core Antigen", <i>Vaccine</i> (1996) <b>14</b> (6):545-552					
	B53	LUCKOW, "Insect Cell Expression Technology" Chapter 7 in <i>Protein Engineering: Principle and Practice</i> , J.L. Cleland et al. eds., Wiley-Liss, Inc. (1996) pages 183-218					
	B54	LUCKOW et al., "Efficient Generation of Infectious Recombinant Baculoviruses by Site-Specific Transposon-Mediated Insertion of Foreign Genes into a Baculovirus Genome Propagated in <i>Escherichia coli</i> ", <i>J. Virol.</i> (August 1993) <b>67</b> (8):4566-4579					
	B55	MATTEUCCI et al., "Synthesis of Deoxyoligonucleotides on a Polymer Support", <i>J. Am. Chem. Soc.</i> (1981) <b>103</b> :3185-3191					
	B56	MILICH et al., "Conversion of Poorly Immunogenic Malaria Repeat Sequences into a Highly Immunogenic Vaccine Candidate", <i>Vaccine</i> (2002) <b>20</b> :771-788					
	B57	NARDELLI-HAEFLIGER et al., "Oral and Rectal Immunization of Adult Female Volunteers with a Recombinant Attenuated <i>Salmonella typhi</i> Vaccine Strain", <i>Infect. and Immun.</i> (December 1996) <b>64</b> (12):5219-5224					
	B58	NASSAL et al., "An Intramolecular Disulfide Bridge between Cys-7 and Cys61 Determines the Structure of the Secretory Core Gene Product (e Antigen) of Hepatitis B Virus", <i>J. Virol.</i> (July 1993) <b>67</b> (7):4307-4315					
	B59	ODELL et al., "Identification of DNA Sequences Required for Activity of the Cauliflower Mosaic Virus 35S Promoter", <i>Nature</i> (February 1985) <b>313</b> :810-812					
	B60	ONO et al., "The complete nucleotide sequences of the cloned hepatitis B virus DNA; subtype adr and adw", <i>Nucleic Acids Res.</i> (1983) <b>11</b> (6):1747-1757					
	B61	PASEK et al., "Hepatitis B virus genes and their expression in <i>E. coli</i> ", <i>Nature</i> (December 1979) <b>282</b> :575-579					
	B62	PASZKOWSKI et al., "Direct Gene Transfer to Plants", <i>EMBO J.</i> (1984) <b>3</b> (12):2717-2722					
	B63	ROGERS et al., "Improved Vectors for Plant Transformation: Expression Cassette Vectors and New Selectable Markers", <i>Meth. in Enzymol.</i> (1987) <b>153</b> :253-277					
	B64	SALFELD et al., "Antigenic Determinants and Functional Domains in Core Antigen and e Antigen from Hepatitis B Virus", <i>J. Virol.</i> (February 1989) <b>63</b> (2):798-808					
	B65	SALLBERG et al., "A Malaria Vaccine Candidate Based on a Hepatitis B Virus Core Platform", <i>Intervirology</i> (2002) <b>45</b> :350-361					
	B66	SCHERLE et al., "Functional Analysis of Influenza-Specific Helper T Cell Clones in Vivo", <i>J. Exp. Med.</i> (October 1986) <b>164</b> :1114-1128					
	B67	SCHODEL et al., "Recombinant HBV Core Particles Carrying Immunodominant B-Cell Epitopes of the HBV Pre-S2 Region", <i>Vaccines</i> (1990) <b>90</b> , Cold Spring Harbor Laboratory, New York, pp.193-198					
	B68	SCHODEL et al., "Hybrid Hepatitis-B Virus Core/Pre-S Particles Expressed In Live Attenuated <i>Salmonellae</i> for Oral Immunization", <i>Vaccines</i> (1991) <b>91</b> , Cold Spring Harbor Laboratory, New York, pp.319-325					
	B69	SCHODEL et al., "The Position of Heterologous Epitopes Inserted in Hepatitis B Virus Core Particles Determines Their Immunogenicity", <i>J. Virol.</i> (January 1992) <b>66</b> (1):106-114					
	B70	SCHODEL et al., "Structure of Hepatitis B Virus Core and e-Antigen", <i>J. Biological Chemistry</i> (1993) <b>268</b> (2): 1332-1337					
	B71	SEEGER et al., "Nucleotide Sequence of an Infectious Molecularly Cloned Genome of Ground Squirrel Hepatitis Virus", <i>J. Virol.</i> (August 1984) <b>51</b> (2):367-375					
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(4564-81175)

Serial No.  
09/930,915

# INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

Applicants  
Ashley J. Birkett

Filing Date  
August 15, 2001

Group  
1648

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

- |     |  |
|-----|--|
| B73 | TACKET et al., "Safety and Immunogenicity in Humans of an Attenuated <i>Salmonella typhi</i> Vaccine Vector Strain Expressing Plasmid-Encoded Hepatitis B Antigens Stabilized by the Asd-Balanced Lethal Vector System", <i>Infect. &amp; Immun.</i> (August 1997) <b>65</b> (8):3381-3385 |
| B74 | TREANOR et al., "Passively Transferred Monoclonal Antibody to the M2 Protein Inhibits Influenza A Virus Replication in Mice", <i>J. Virol.</i> (March 1990) <b>64</b> (3):1375-1377  |
| B75 | TSUDA et al., "Application of the Human Hepatitis B Virus Core Antigen from Transgenic Tobacco Plants for Serological Diagnosis", <i>Vox Sang</i> (1998) <b>74</b> :148-155  |
| B76 | TWELL et al., "The 5'-Flanking DNA of a Patatin Gene Directs Tuber Specific Expression of a Chimaeric Gene in Potato", <i>Plant Mol. Biol.</i> (March 1987) <b>9</b> :365-375  |
| B77 | VALENZUELA et al., "Purification of the Recombinant Hepatitis B core Antigen, and Its Potential Use for the Diagnosis of Hepatitis B Virus Infection", <i>Biotechnologia Aplicada</i> (2002) <b>19</b> (3):136-142   |
| B78 | VODKIN et al., "ca Lectin Gene Insertion has the Structural Features of a Transposable Element", <i>Cell</i> (1983) <b>34</b> :1023-1031   |
| B79 | WASENAUER et al., "Relevance of Cysteine Residues for Biosynthesis and Antigenicity of Human Hepatitis B Virus e Protein", <i>J. Virol.</i> (March 1993) <b>67</b> (3):1315-1321   |
| B80 | WENZLER et al., "Analysis of a Chimeric Class-I Patatin-GUS Gene in Transgenic Potato Plants: High-Level Expression in Tubers and Sucrose-Inducible Expression in Cultured Leaf and Stem Explants", <i>Plant Mol. Biol.</i> (1989) <b>12</b> :41-50  |
| B81 | YAMAMOTO et al., "Characterization of cis-Acting Sequences Regulating Root-Specific Gene Expression in Tobacco", <i>The Plant Cell</i> (April 1991) <b>3</b> :371-382  |
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| B83 | YOUVAN et al., "Light-harvesting II (B800-B850 Complex) Structural Genes from <i>Rhodospseudomonas capsulata</i> ", <i>Proc. Natl. Acad. Sci. USA</i> (January 1985) <b>82</b> :58-62  |
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| B85 | ZHENG et al., "The Structure of Hepadnaviral Core Antigens", <i>J. Biol. Chem.</i> (1992) <b>267</b> (13):9422-9429  |

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